



Express Mail No. EV 313 842 229 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Parkin and Ziermann  
Serial No.: 09/766,344  
Filed: January 19, 2001  
For: Means and Methods for  
Monitoring Protease Inhibitor  
Antiretroviral Therapy and  
Guiding Therapeutic Decisions  
in the Treatment of HIV Aids

Confirmation No.: 7661  
Art Unit: 1648  
Examiner: S. Foley  
Attorney Docket No: 011068-0034-2000

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR § 1.136(a)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

It is respectfully requested that the time for response to the Office Action dated October 21, 2002 be extended for a period of Five (5) month(s) from April 17, 2003 to and including November 14, 2003.

The fee for this extension is estimated to be \$2,010.00. Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A copy of this sheet is enclosed.

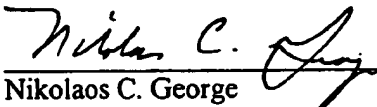
Date: November 14, 2003

Adjustment date: 01/15/2004 EEKUBAY1  
11/20/2003 AMONDAF1 00000049 161150 09766344  
04 FC:1255 2010.00 CR

11/20/2003 AMONDAF1 00000049 161150 09766344  
04 FC:1255 2010.00 DA

01/15/2004 EEKUBAY1 00000013 161150 09766344  
04 FC:2255 1005.00 DA

Respectfully submitted,

  
Nikolaos C. George 39,201  
PENNIE & EDMONDS LLP (Reg. No.)  
3300 Hillview Avenue  
Palo Alto, California 94304  
(650) 493-4935



11-12-03

RCE/1600

PTO/SB/30 (5/2000)

Approved for use through 12/31/2000. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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# REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

Express Mail No	EV 313 842 229 US
Application Number	09/766,344
Filing Date	January 19, 2001
First Named Inventor	Parkin and Ziermann
Group Art Unit	1648
Examiner Name	S. Foley
Attorney Docket No.	011068-0033-999

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TECH CENTER 1600/290

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

**NOTE:** 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Interim Rule, 65 Fed. Reg. 14863 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000) which established RCE practice.

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TECH CENTER 1600/2900

## 1. Submission required under 37 C.F.R. § 1.114

- a. ☐ Previously submitted
- i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on \_\_\_\_\_  
(Any unentered amendment(s) referred to above will be entered).
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed \_\_\_\_\_
- iii. ☐ Other \_\_\_\_\_
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☐ Affidavit(s)/Declaration(s)
- iii. ☐ Information Disclosure Statement (IDS)
- iv. ☐ Other \_\_\_\_\_

11/20/2003 AWONDAF1 00000049-161150 09766344

01 FC:1801 770.00 DA  
02 FC:1202 162.00 DA  
03 FC:1201 344.00 DA

Adjustment dated 01/15/2004 EEKUBAY1  
11/20/2003 AWONDAF1 00000049 161150 09766344  
01 FC:1801 770.00 CR  
02 FC:1202 162.00 CR  
03 FC:1201 344.00 CR

## 2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of \_\_\_\_\_ months.  
(Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(f) required)
- b. ☐ Other \_\_\_\_\_

## 3. Fees

The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed

- a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Pennie & Edmonds LLP Deposit Account No. 16-1150:
- i. ☒ RCE fee required under 37 C.F.R. § 1.17(e), estimated to be \$ 770.00
- ii. ☒ Extension of time fee required under 37 C.F.R. §§ 1.136 and 1.17, estimated to be \$ 2,010.00 for a five month extension, the request for which is being made herewith
- iii. ☒ Other (Please see attached Amendment Fee Transmittal Sheet)
- b. ☐ Check in the amount of \$ \_\_\_\_\_ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	Nikolaos C. George	Registration No. (Attorney/Agent)	39,201
Signature	<i>Nikolaos C. George</i>	Date	November 14, 2003

## CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner For Patents, P.O. Box 1450, Mail Stop RCE, Alexandria, VA 22313-1450, or by facsimile transmitted to fax no. 1-703- to the U.S. Patent and Trademark Office on the date indicated below.

Name (Print/Type)		Registration No. (Attorney/Agent)	
Signature		Date	

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND Fees and Completed Forms to the following address: Commissioner for Patents P.O. Box 1450, Mail Stop RCE, Alexandria, VA 22313-1450.

01/15/2004 EEKUBAY1 00000013 161150 09766344

01 FC:2801 385.00 DA  
02 FC:2202 72.00 DA  
03 FC:2201 172.00 DA

NY2: 1480830.1

12-24-03

DEP 25

Room 307

Express Mail No.: EV 313 842-609 US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE, 16-6 27

Application of: Parkin et al.

Confirmation No.: 7661

US PATENT & TRADEMARK  
OFFICE

Application No.: 09/766,344

Group Art Unit: 1648

Filed: January 19, 2001

Examiner: S. Foley

For: MEANS AND METHODS FOR  
MONITORING PROTEASE  
INHIBITOR ANTIRETROVIRAL  
THERAPY AND GUIDING  
THERAPEUTIC DECISIONS IN THE  
TREATMENT OF HIV/AIDS

Attorney Docket No.: 11068-033-999

REQUEST FOR REFUND

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Fees in excess of the required fees were paid in connection with the above-identified patent application. In particular:

- (1) extra claim fees in the amount of \$506.00 (for an Amendment) on November 14, 2003;
- (2) an extension of time fee in the amount of \$2,010.00 (5 months) on November 14, 2003; and
- (3) a Request for Continued Examination fee in the amount of \$770.00 on November 14, 2003.

The Assignee, ViroLogic, Inc., qualifies as a small entity under by virtue of a Verified Statement (Declaration) Claiming Small Entity filed with the U.S. Patent and Trademark Office on May 21, 2001 (a copy of which is attached hereto).

Accordingly, please refund 50% of the fees by crediting Pennie & Edmonds Deposit Account No. 16-1150 as follows:

(1) \$253.00 for extra claim fees from an Amendment filed November 14, 2003;

(2) \$1,005.00 for an extension of time filed November 14, 2003;

(3) \$385.00 for a Request for Continued Examination filed November 14, 2003.

PATENT & TRADEMARK  
OFFICE


774 JAN -6 PM 2:17

US PATENT & TRADEMARK  
OFFICE

A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: December 22, 2003



42,983

Rahul Pathak for  
Nikolaos C. George (Reg. No. 39,201)  
PENNIE & EDMONDS LLP  
1155 Avenue of the Americas  
New York, N.Y. 10036-2711  
(212) 790-7900

(Reg. No.)



Applicant or Patentee: Neil T. Parkin and Rainer A. Ziermann Attorney's JPW/CMR  
Serial or Patent No.: 09/766,344 Docket No.: 59597-D  
Filed or Issued: January 19, 2001  
Title of Invention or Patent: MEANS AND METHODS FOR MONITORING PROTEASE INHIBITOR  
ANTIRETROVIRAL THERAPY AND GUIDING THERAPEUTIC  
DECISIONS IN THE TREATMENT OF HIV/AIDS

VERIFIED STATEMENT (DECLARATION) CLAIMING  
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)  
AND §1.27(d) - SMALL BUSINESS CONCERN

PATENT & TRADEMARK OFFICE  
JAN 19 2001

I hereby declare that I am:

2001 JAN -6 PM 2:24

the owner of the small business concern identified below.

☒ an official of the small business concern empowered to act on behalf of the  
concern identified below:

Name of Concern: ViroLogic, Inc.

Address of Concern: 270 East Grand Avenue  
South San Francisco, CA 94080

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. §121.3-18, reproduced in 37 C.F.R. §1.9(d), for purposes of paying reduced fees under 35 U.S.C. §41(a) and §41(b), in that the number of employees of the concern, including those of its affiliates, does not exceed five hundred (500) persons. For purposes of this verified statement, the number of employees of the business concern is the average number, over the previous fiscal year, of the persons employed by the business concern on a full-time, part-time, or temporary basis during each pay period of the fiscal year, and concerns are affiliates of each other when, either directly or indirectly, one concern controls or has power to control the other, or a third party or parties controls or has power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled

MEANS AND METHODS FOR MONITORING PROTEASE INHIBITOR ANTIRETROVIRAL THERAPY AND  
GUIDING THERAPEUTIC DECISIONS IN THE TREATMENT OF HIV/AIDS  
described in:

☒ the specification filed herewith  
☒ application serial no. 09/766,344 filed January 19, 2001  
patent no. \_\_\_\_\_ issued \_\_\_\_\_

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below<sup>a</sup> and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. §1.9(c)\*, any concern which could not qualify as a small business concern under 37 C.F.R. §1.9(d)\* or as a nonprofit organization under 37 C.F.R. §1.9(e)\*.

Name: N/A

Address: \_\_\_\_\_

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

<sup>a</sup> NOTE: Separate verified statements are required for each named person, concern, or organization to the invention availing to their status as small

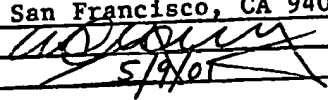
Small Entity/Small Business Concern  
Page -2-

PATENT & TRADEMARK  
OFFICE

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)\*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Mr. William D. Young  
Title In Organization: Chairman and CEO  
Address: ViroLogic, Inc., 270 East Grand Avenue  
South San Francisco, CA 94080  
Signature:   
Date Of Signature: 5/9/05



Express Mail No.: **EV 313 842 609 US**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

2001 JAN -6 PM 2:20

US PATENT & TRADEMARK  
OFFICE

Application of: *Parkin et al.*

Confirmation No.: 7661

Application No.: 09/766,344

Group Art Unit: 1648

Filed: January 19, 2001

Examiner: S. Foley

For: MEANS AND METHODS FOR  
MONITORING PROTEASE  
INHIBITOR ANTIRETROVIRAL  
THERAPY AND GUIDING  
THERAPEUTIC DECISIONS IN THE  
TREATMENT OF HIV/AIDS

Attorney Docket No.: 11068-033-999

### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

☐ Each U.S. patent application publication and U.S. and foreign patent;

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

PATENT MAINTENANCE  
DIVISION

☐ Before the mailing of the first Office action on the merits;

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☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

US PATENT & TRADEMARK  
OFFICE

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.

3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:  
☐ enclosed  
☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

☐ enclosed.  
☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☒ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).



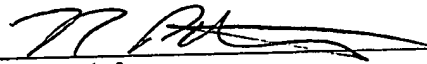
(Check appropriate Items 6a, 6b and/or 6c)

PATENT MAINTENANCE  
FEE

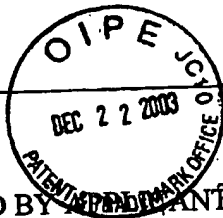
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No., filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §1.97(g) and (h).

Respectfully submitted,

Date: December 22, 2003

  
Rahul Pathak for  
Nikolaos C. George (Reg. No. 39,201)  
**PENNIE & EDMONDS LLP**  
1155 Avenue of the Americas  
New York, N.Y. 10036-2711  
(212) 790-7900

42,983  
(Reg. No.)



**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.  
11068-033-999

APPLICATION NO  
09/766,344

APPLICANT  
Parkin et al.

FILING DATE  
January 19, 2001

GROUP  
1648

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

A01

Hazuda, et al., (1998) "Inhibitors of Strand Transfer That Prevent Integration and Inhibit HIV-1 Replication In Cells," *Science* (2000) 287:646-650.

**EXAMINER**

**DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.